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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,342	08/01/2003	Christopher A. Jethrow	ST8636US	3736
7590	01/06/2005		EXAMINER	
Mark Kusner Mark Kusner Co., LPA Highland Place - Suite 310 6151 Wilson Mills Road Highland Heights, OH 44143			JASTRZAB, KRISANNE MARIE	
			ART UNIT	PAPER NUMBER
			1744	
			DATE MAILED: 01/06/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/633,342	JETHROW ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Krisanne Jastrzab	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1-8 and 10-22 is/are rejected.
- 7) Claim(s) 9 is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | Paper No(s)/Mail Date. ____   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: ____                                     |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4, 7 and 10-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 2, the recitation of "said valve assembly" is found to be vague and indefinite because both a "overflow valve assembly" and a "filter valve assembly" were previously disclosed so it is unclear which is being referred to. Further, "said interior assembly" lacks proper antecedent basis.

With respect to claim 4, "said first sensing element" lacks proper antecedent basis.

With respect to claim 7, ht use of "like components" is found to be vague and indefinite because it is unclear as to what would constitute "like components".

With respect to claim 10, this claim is found to be vague and indefinite because it improperly attempts to further limit the microbial deactivation fluid, however, the presence of that fluid was not properly, positively provided previously.

With respect to claim 11, this claim lacks proper legal phraseology such as "comprising" to delineate the body of the claim. Also, the reference to "said bacteria-retentive filter medium" lacks proper antecedent basis. Clarification is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-12 and 15-16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Meierhoefer U.S. patent No. 4,533,068.

Meierhoefer teaches a sterile solution deliver device constructed having a filter canister connected to a fluid passage and with a filter assembly containing a bacteria-retentive filter and valve means allowing for air flow in only one direction, the entire assembly being sterile. See column 4, lines 40-68, column 5, lines 10-15 and lines 30-60, column 7, lines 25-30 and lines 45-50.

Claims 11-12, 15-16 and 19-20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kravolic et al., U.S. patent No. 4,731,222.

Kravolic et al., teach an air inlet valve assembly 80 selectively interconnectable with an automated liquid sterilization system, which selectively interconnects the interior of a reservoir with a source of sterile air. Within the valve passage is a sterilizing filter that removes bacteria. See column 6, lines 34-40 and lines 54-56, and Fig. 1.

Claims 11-18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hopkins et al., U.S. patent No. 5,928,516.

Hopkins et al., teach a filter assembly containing a bacteria-retentive filter effective to 0.02 microns made of PTFE within a sterile canister intended for installation on a housing. See column 5, lines 1-5, column 7, lines 40-54, and column 8, lines 1-15.

Claims 11-12, 15-16 and 19-20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Siegel et al., U.S. patent No. 5,217,698.

Siegel et al., teach an air inlet valve assembly selectively inter-connectable with an automated liquid sterilization system, which selectively interconnects the interior of a reservoir with a source of sterile air. Within the valve passage is a sterilizing filter that removes bacteria. See column 6, lines 53-63.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13-14, 17-18 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siegel et al., as applied to claims 11-12, 15-16 and 19-20 above, and further in view of Hopkins et al.

Both references are applied as set forth above:

It would have been obvious to one of ordinary skill in the art that the bacteria-retentive filter of Siegel et al., be constructed of a material as recited in Hopkins et al., because Hopkins et al., teach such material as being conventionally recognized for providing effective, optimal sterile filtration required in sterile liquid systems.

Claims 1-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siegel et al., together with Meierhoefer.

Siegel et al., teach, in addition to that cited above, an automated liquid sterilization system for use with a removable cassette providing the sterilization chamber. The system includes manifold means for the circulation of a sterilant such as peracetic acid via automated valved control, through the cassette when it is in place for sterilization. An overflow protection means is provided to ensure that the integrity of the system is not compromised by back flow or over pressure. Siegel et al., teach that the

system is modular and that operating parameters are sensed and controlled. See column 5, lines 40-50 and 58-60, column 6, lines 5-12, and lines 26-63, column 7, lines 40-50.

Meierhoefer teaches, in addition to that structure set forth above, actuation and control of delivery and venting of a solution based on pressurization, such that delivery and venting act as check valving. See column 4, lines 40-50.

It would have been well within the purview of one of ordinary skill in the art to employ the delivery and venting configuration as taught in Meierhoefer, in the modular system of Siegel et al., to provide effective delivery based on the system parameters with the simplified check valve/overflow protection.

With respect to claims 4-5, Siegel et al., teaches sensing and control system operating parameters which include as conventionally recognized in circulating liquid systems, level and flow.

#### ***Allowable Subject Matter***

Claim 9 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

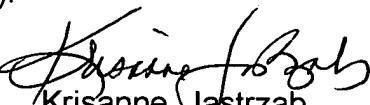
The following is a statement of reasons for the indication of allowable subject matter: the closest prior art of record fails to teach or suggest the claimed semi-hemispherical construction and associated placement of the overflow port and overflow valve assembly.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krisanne Jastrzab whose telephone number is 571-272-1279. The examiner can normally be reached on Mon.-Wed. 6:30am-4:00pm and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Krisanne Jastrzab  
Primary Examiner  
Art Unit 1744

January 5, 2005